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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,901

Applicant(s)

D'AMELIO ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-30, 32-42, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 10, 31 and 43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0604 & 0105</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-45 are presented for examination on the merits.

Claim Objections

Claims 1-45 are objected to because of the following informalities: Throughout the claims (including all independent claims), as well as throughout the specification, the genus "*Rosmarinum*" is apparently misspelled. The correct spelling for this plant (rosemary) genus is --*Rosmarinus*-- (as evidence - see, e.g., Castleman: "The Healing Herbs", page 311). The specification should also be amended accordingly (at least once therein - e.g., in the Abstract).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 6, 14-19, 21-23, 26, 27, 29, 30, and 35-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Oh (KR 2002057448 - DWPI English Abstract).

An antimicrobial composition comprising an effective amount of a mixture of plant materials, whereby the mixture of plant materials comprise *Origanum vulgare* (oregano), *Thymus vulgaris* (thyme), *Rosmarinus officinalis* (rosemary), and *Lavandula officinalis* (lavender) and/or extracts thereof and a process of inhibiting the growth of microorganisms via contacting the microorganisms therewith, is claimed.

Oh teaches an anti-acne (antimicrobial) cosmetic composition having an effective inhibitory activity against pathogenic bacteria (which is inevitably applied to the face including those portions of the face suffering from acne - and, thus, is inevitably contacted with the microorganisms inherently present thereon) comprising a mixture - in substantially equal amounts (i.e., a ratio of 5:3:3:3, respectively) - of lavender, thyme, oregano, and rosemary essential oils as active ingredients therein (please note that essential oils read upon plant material as well plant extracts since plant essential oils are oil which are inherently extracted therefrom). The reference antimicrobial composition further comprises cinnamon essential oil as an active ingredient therein. The cosmetic composition is provided in a base material which would be capable of supporting the growth of microorganisms (i.e., under the correct environmental conditions, nothing would preclude the growth of microorganisms therein - in the absence of the antimicrobial essential oils) - see DWPI English Abstract. Please also note that the base material (such as defined by instant claims 21) further reads upon facial skin to which the cosmetic composition is applied to (and, thus, coats). The various cosmetic forms taught by the reference would inherently comprise an admixed component from among those instantly claimed (such as a dispersing agent, emulsifying agent, and/or anti-caking agent - e.g., soap would inherently contain an admixed surfactant/detergent therein, which reads upon a dispersing agent; creams/lotions would inherently contain an admixed emulsifying agent therein; foundations would inherently contain an anti-caking agent therein - in combination with the reference mixture of plant essential oils). In addition, the antimicrobial composition taught by the cited reference would inherently provide an inhibitory effect toward the particular bacterial and yeast strains instantly claimed. Further, with respect to the instantly claimed limitation concerning the

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plant materials being in an amount to provide an inhibitory amount of one or more of the recited compounds, please note that naturally-occurring antimicrobial compounds within the reference essential oils would inherently be within such amounts. For example, please note that thyme essential oil is well recognized in the herbal art to inherently contain the naturally-occurring antimicrobial compounds carvacrol and thymol therein (as evidence - see, e.g., Castleman, "The Healing Herbs", paragraph bridging pages 352-353). Such antimicrobial compounds would inherently be in amount(s) to provide such antimicrobial activity.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9, 14-23, 26-30, 32-42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oh (KR 2002057448 - DWPI English Abstract) in view of Murad (US 6,296,880) and Wiegand et al. (US 2002/0034489).

The reference by Oh is relied upon for the reasons set forth above. Oh does not expressly teach the further inclusion of *Hydrastis canadensis* (goldenseal) or olive leaf extract within such an anti-acne/antimicrobial composition.

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Murad beneficially teach a goldenseal is useful within topical skin formulations as an effective antimicrobial agent therein, including for use in treating acne (see, e.g., col 6, line 50 - col 7, line 30).

Wiegand et al. teach a that olive leaf (and derivatives thereof - e.g., extract) is a well known to be beneficially useful as an effective anti-acne agent within topical compositions (see, e.g., paragraph [0092]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit (e.g., as an antimicrobial for treating acne) since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose - as well as to use such a composition for that purpose: e.g., to topically treat acne. The idea for combining them flows logically from their having been used individually in the prior art. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (such as reasonably disclosed by the instant teachings with

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respect to the amount ranges of ingredients recited in instant claims 10, 31, and 43 - please note that the instant specification reasonably discloses that the combined recited amount ranges of the claimed ingredients within claims 10, 31, and 43 provide a synergistic formulation: see, e.g., paragraphs [0025] and [0035], and Examples 1 and 4, of the instant specification). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (i.e., other than the overall synergistic amount ranges of the combined mixture of herbals set forth in claims 10, 31, and 43 as discussed above, the judicious selection of an appropriate amount range for certain other claimed ingredients such as cinnamon, goldenseal, or olive leaf extract is deemed routine optimization).

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Claims 1-9, 14-30, 32-42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (US 4,380,506), Kaneka Sunspice KK (JP 08020510 - DWPI English Abstract), Jampani et al. (US 6,248,343), Castleman (The Healing Herbs, 1991), and Albacarys et al. (US 6,338,855).

Kimura et al. beneficially teach an antimicrobial/antibacterial composition comprising spice herbs such as oregano, rosemary, and thyme extracts as active antimicrobial agents therein. Kimura et al. further teach that the antimicrobial/antibacterial composition advantageously acts as a preservative when added to foods, cosmetics, and medicines (see entire document including Abstract; col 1, lines 5-55; col 2, lines 13-25; col 4, lines 31-47; Examples 1-3, and claim 1).

Kaneka Sunspice KK beneficially teaches an antimicrobial/antibacterial composition, including for use as a drug or within food, which comprises oregano, rosemary, and cinnamon extracts, as active ingredients therein (see DWPI English Abstract).

Jampani et al. beneficially teach an antimicrobial/antibacterial composition which preferably and advantageously comprises thyme oil, lavender oil, and goldenseal, in part so as to provide enhanced efficacy of the antimicrobial composition (see entire document including col 3, lines 8-14; col 4, lines 30-34; col 6, lines 48-59; col 8, lines 6-7; col 9, line 64; claims 4 and 19).

Castleman beneficially teaches that several of the instantly claimed herbal ingredients are well known in the art to be useful as active antimicrobial/antibacterial agents including thyme oil (which Castleman discloses contains the naturally-occurring antimicrobial compounds thymol and carvacrol therein) and goldenseal, as well as rosemary and cinnamon (see pages 115-117, 201-204, 311-313, and 351-354).

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Albacarys et al. beneficially teach that several of the instantly claimed herbal ingredients are well known in the art to be useful as active antimicrobial/antibacterial agents including olive leaf extract, as well as cinnamon, lavender, rosemary, and thyme (see, e.g., col 18, line 19 - col 19, line 24).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit (i.e., effective antimicrobial/antibacterial agents) since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose - as well as to use such a composition for that purpose: e.g., to inhibit the growth of microorganisms within a cosmetic, food, and/or medicine. The idea for combining them flows logically from their having been used individually in the prior art. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (such as reasonably disclosed by the instant teachings with respect to the amount ranges of ingredients recited in instant claims 10, 31, and 43 - please note that the instant specification reasonably discloses that

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the combined recited amount ranges of the claimed ingredients within these claims provide a synergistic formulation: see, e.g., paragraphs [0025] and [0035], and Examples 1 and 4, of the instant specification). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (i.e., other than the overall synergistic amount ranges of the combined mixture of herbals set forth in claims 10, 31, and 43 as discussed above, the judicious selection of an appropriate amount range for certain other claimed ingredients such as cinnamon, goldenseal, or olive leaf extract is deemed routine optimization).

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 10, 31, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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To overcome the above rejections, as well as to hasten prosecution, it is suggested that claims 10, 31, and 43 be appropriately incorporated into independent claims 1, 18, and 35, respectively.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1655